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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,234	10/21/2005	Makoto Kobayashi	68116(46342)	6538

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EDWARDS ANGELL PALMER & DODGE LLP  
P.O. BOX 55874  
BOSTON, MA 02205

EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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12/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/554,234

**Applicant(s)**

KOBAYASHI ET AL.

**Examiner**

John D. Ulm

**Art Unit**

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1 to 4, in so far as they relate to SEQ ID NOs:1 and 3.

Group II, claims 1 to 4, in so far as they relate to SEQ ID NOs:1 and 4.

Group III, claims 1 to 4, in so far as they relate to SEQ ID NOs:1 and 5.

Group IV, claims 1 to 4, in so far as they relate to SEQ ID NOs:1 and 6.

Group V, claims 1 to 4, in so far as they relate to SEQ ID NOs:1 and 7.

Group VI, claims 5 and 6, drawn to a compound of unspecified constitution that effects the binding of a peptide ligand to a receptor protein of SEQ ID NO:1.

Group VII, claim 7, drawn to a method of identifying an agonist of a receptor protein of SEQ ID NO:1 by measuring the effects of a compound upon receptor-mediated adenylate cyclase activity.

Group VIII, claims 8, 14 and 16, in so far as they relate to a receptor protein of SEQ ID NO:1 and method of treatment.

Group IX, claims 9, 10, 14 and 16, in so far as they relate to a nucleic acid encoding a receptor protein of SEQ ID NO:1 and method of treatment.

Group X, claims 11, 12, 15 and 17, in so far as they are drawn to an antibody and method of use.

Group XI, claims 13, 15 and 17, in so far as they relate to an antisense nucleic acid and method of use.

Group XII, claims 14 and 16, in so far as they relate to an agonist of unspecified constitution and method of use.

Group XIII, claims 15 and 17, in so far as they relate to an antagonist of unspecified constitution and method of use.

The inventions listed as Groups I to XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The second and third paragraphs on page one of the instant specification show that a receptor protein of SEQ ID NO:1 and a peptide agonist thereto were known in the art before the making of the instant invention. Therefore, the combination of a receptor protein of SEQ ID NO:1 and a peptide agonist thereto is not a distinguishing inventive concept. Because the amino acid sequences presented in SEQ ID NOs:3 to 7 of the instant application do not share a substantial structural feature that distinguishes those five sequences as a group from related sequences of the prior art, the relationship between each of these sequences and a receptor protein of SEQ ID NO:1 is independent from the relationship between any of the other recited sequences and that receptor protein. In other words, inventions I to V do not reflect a common inventive concept because SEQ ID NOs: 3 to 7 do not share a common utility that is based upon

a common structural feature or combination of features that distinguishes them as a group from polypeptides of the prior art and their relationship to a receptor protein of SEQ ID NO:1 is not unique.

The competitive ligand of invention VI, the protein of invention VIII, the nucleic acid of invention IX, the antibody of invention X, the antisense molecule of invention XI, the agonist of invention XII and the antagonist of invention XIII do not reflect a common inventive concept because they are six structurally unrelated compounds that lack a common utility that is based upon a common substantial structural feature or combination of features that distinguishes them as a group from related compounds of the prior art. These compounds are distinct because each can be made and used without the others. Further, the instant specification has expressly conceded the a receptor protein of SEQ ID NO:1, a nucleic acid encoding that protein and an agonist thereto to the prior art. In addition, because a receptor protein of SEQ ID NO:1 was known in the prior art, the relationship between that protein and adenylate cyclase activity, upon which invention VII is based, is an inventive concept that is independent from the receptor protein employed therein and which is not reflected in any of the other claimed inventions.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

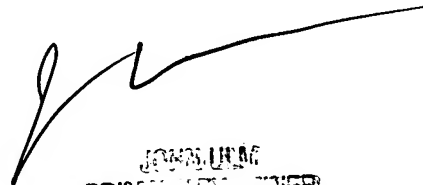
Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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